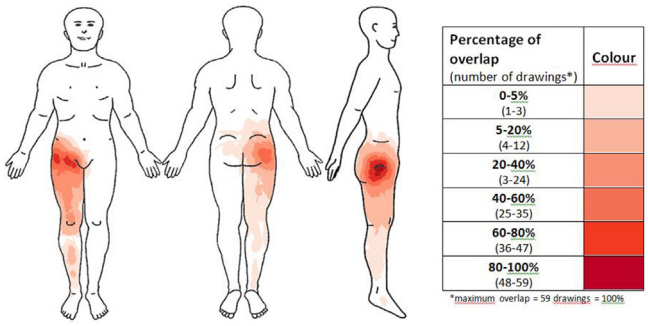
Methods: Primary care patients with unilateral clinical and radiographic hip OA, participating in a randomized clinical trial, recorded at baseline pain intensity using an 11-box numeric rating scale, pain duration in months and the distribution of hip pain using a manikin displaying three separate views: front, back and lateral. Pain drawings were analysed using a template to determine pain locations and distribution of pain. Drawings were subsequently digitally processed to produce a composite image using colours to illustrate frequency.
Results: A total of 108/109 (99%) patients completed pain drawings according to instructions. One drawing consisted of a single line but the identified areas were included in the analyses of pain location and the composite image. The mean age was 65 (SD 9), 44% were females, the right/left hip ratio was 66/43 respectively, the mean pain duration was 32 months (SD 36, range 4–300), and mean pain intensity was 5.4 (SD 2.0). A total of 77% had marked the area of the greater trochanter, 53% the groin, 42% the anterior/lateral thigh, 38% the buttock, 17% the knee and 15% the lower leg. Less than 20% of the patients reported pain in only one area, most commonly the greater trochanter area (16%). Between 1-2% of the patients reported pain only at the groin, buttock or anterior/lateral thigh. No patients marked pain exclusively in the areas of the knee, posterior thigh or lower leg. The composite images of the cumulated pain drawings in the three planes are illustrated in Figure 1.
Conclusions: To our knowledge, this is the first study describing pain location and distribution in a cohort of patients presenting to primary care with hip pain and unilateral hip OA. In descending order, the most common pain locations are the greater trochanter, groin, thigh and buttock areas. No patients with hip OA reported pain exclusively in the knee or to the lower leg areas. When adult patients in primary care present with pain in the greater trochanter, groin, anterior lateral thigh or buttock areas, the clinician as a minimum should include a physical examination of the hip joint.

Figure 1. Cumulative pain drawings demonstrating pain location and pain distribution of 109 patients with unilateral hip OA.



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CONCERNS IMPORTANT TO ELDERLY PATIENTS WITH HAND OSTEOARTHRITIS: A QUALITATIVE MULTI-ETHNIC ASIAN STUDY

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Purpose: Hand osteoarthritis (HOA) is common but little is known about how to measure the impact on disability and quality of life (QoL) among patients with HOA. None of the existing HOA specific instruments was patients-derived. With the ageing population, there is a need to develop instruments in patients' perspective for measuring disability and QoL for use in future drug trials. We aim to identify important concerns among patients suffering from symptomatic HOA in Singapore. It is the first study with participation of patients from the Asian socio-cultural context.
Methods: A qualitative study using a focus group technique was performed. Patients with symptomatic HOA according to American college of Rheumatology Classification criteria were recruited from outpatient clinic of a tertiary centre. Focus groups were conducted as stratified by gender, ethnicity and language. All discussions were audio-taped and analyzed in an inductive approach. Areas of concern important to study participants were then compared to the following commonly used HOA specific instruments: FIHOA, SACRAH, AUSCAN and HAQ.
Results: Twenty-six patients [23 women, 3 men; 23 Chinese and 3 Malay; mean (SD) age 62.9 (7.5) years] participated in seven focus groups. Two and five focus groups were conducted in Chinese and English respectively. The qualitative analysis revealed detailed descriptions of pain sensations at different qualities, and its relation to activity and environment, none of which were fully represented in the existing instruments. Psychological consequences, aesthetic concerns, participation in leisure activities, participation in family roles and social activities are important concerns from the focus groups which were not covered by the existing instruments. Important QoL concerns that impact on the Asian style of living including eating, cooking and praying was revealed. Impact on work productivity by HOA was also revealed. Out of the 59 concerns among patients with HOA, only 16 concerns (27%) were covered with the existing instruments.
Conclusions: The concerns important to HOA patients are not fully represented in the most commonly used instruments, which were not patient-derived. This qualitative study helps to refine the concerns of people with HOA in patients' perspectives. It gives information on selection of domains for the development of instrument that measure QoL of HOA patients.

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THE ROLE OF cYTOKINES IN PATIENTS WITH OSTEOARTHRITIS AND TYPE 2 DIABETES MELLITUS

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Purpose: to investigate influence of concentration in plasma tumor necrosis factor-α (TNF-α), interleukin-1β (IL-1β) on articular syndrome and parameters of carbohydrate metabolism in patients with osteoarthritis (OA) and type 2 diabetes mellitus (T2DM).
Methods: The study was performed on 65 patients (29 males), aged 57.9 ± 3.2 with combination OA and T2DM in Regional Hospital of Kharkov. Baseline characteristics of patients included history of OA (7.1 ± 2.3 years), T2DM (8.1 ± 2.5 years). All patients were divided into 2 groups: group 1 (n = 30) – with combined course of OA and T2DM with normal body weight, group 2 (n = 35) – with combined course of OA and T2DM with obesity (BMI≥ 30 kg/m^2). The survey plan included: anthropometric data, indices of carbohydrate exchange (insulin, glucose, HbA1C, HOMA-IR) and level of C-reactive protein (CRP). The level of HbA1C was <7.5% in all patients. The level of TNF-α and IL-1β was determined by ELISA. All patients were made X-ray examination of knees.
Results: Significant correlation between TNF-α and CRP was determined in 1st group (r=0.59; p<0.05) and 2nd group (r=0.72; p<0.05), also correlation between IL-1β and CRP was determined in 1st group (r=0.61; p<0.05) and 2nd group (r=0.78; p<0.05). Among the 1st group of patients the level of insulin resistance was correlated with TNF-α (r=0.36; p<0.05) and IL-1β (r=0.42; p<0.05). More significant correlation between TNF-α and glucose (r=0.44; p<0.05), HbA1C (r=0.54; p<0.05), insulin resistance (r=0.74; p<0.05), HOMAIR (r=0.63; p<0.05) and between IL-1β and glucose (r=0.42; p<0.05), HbA1C (r=0.40; p<0.05), insulin resistance (r=0.52; p<0.05), HOMAIR (r=0.50; p<0.05) was determined in 2nd group with comorbid pathology and obesity. We noticed, the degree of X-ray changes (by Kellgren-Lawrence) were more in 2nd group in compare with the 1st group.
Conclusions: Significant correlation between TNF-α, IL-1β and CRP, glucose, HbA1, insulin resistance, HOMA-IR in group of patients with comorbid pathology and obesity means, that obesity is important factor of pathogenesis relationship immune and metabolic processes in patients with OA and T2DM.

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SOLUMATRIX DICLOFENAC SAFETY IN OLDER PATIENTS WITH OSTEOARTHRITIS PAIN

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Purpose: SoluMatrix® diclofenac is a low-dose nonsteroidal anti-inflammatory drug (NSAID) treatment option developed using SoluMatrix Fine Particle Technology™ to provide effective analgesia at lower doses than commercially available diclofenac drug products. SoluMatrix diclofenac was developed to address concerns regarding the risks for dose-related adverse events (AEs) that have led health

authorities to recommend that NSAIDs be prescribed at the lowest dose. SoluMatrix diclofenac is approved for the management of mild to moderate acute pain and osteoarthritis (OA) pain in adults. Based on previous studies that examined the efficacy and safety of SoluMatrix diclofenac, we evaluated the pooled safety of SoluMatrix diclofenac in older patients (≥65 years of age) across two phase 3 studies.

Methods: A 12-week randomized, multicenter, double-blind, parallel-group study enrolled 305 chronic NSAID and/or acetaminophen users, 41 to 90 years of age with symptomatic and radiographically documented (Kellgren-Lawrence grade II or III) OA of the hip or knee. Patients had baseline Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale scores ≥40 mm at baseline and a documented OA pain "flare" (increase in WOMAC pain subscale ≥15 mm) following NSAID/acetaminophen discontinuation. Patients received either SoluMatrix diclofenac capsules 35 mg two or three times daily (BID or TID) or placebo. A 12-month open-label, multicenter study treated 601 chronic NSAID/acetaminophen users, aged 40 to 86 years, with knee and/or hip OA. Patients initially received SoluMatrix diclofenac 35-mg capsules BID; that could be increased to TID and reduced as needed.

Results: Similar proportions of patients reported AEs in the ≥65 years of age group (157/205 [76.6%]) compared with the <65 years of age group (365/500 [73.0%]). In patients ≥65 years of age treated with SoluMatrix diclofenac, the most commonly reported AEs included nausea (18/205, 8.8%), diarrhea (17/205, 8.3%), and upper respiratory tract infection (17/205, 8.3%). In patients <65 years of age treated with SoluMatrix diclofenac, the most commonly reported AEs were headache (40/500, 8.0%), upper respiratory tract infection (34/500, 6.8%), and diarrhea (32/500, 6.4%). Forty-six of the 205 patients ≥65 years of age (22.4%) withdrew from the study due to any AE, whereas 73/500 patients <65 years of age (14.6%) withdrew from the study due to an AE. Few SoluMatrix diclofenac-treated patients experienced AEs reported in class labeling for NSAIDs, including stroke, myocardial infarction, gastrointestinal ulcers, perforation or hemorrhage, or liver function abnormalities and occurred with no major differences among the two age groups (Table). Two patients (<65 years of age) reported myocardial infarctions, which were not considered to be treatment-related; there were no deaths.

Table. Summary of Selected Adverse Events of Special Interest by Organ System

	≥ 65 Years of Age	< 65 Years of Age	Overall
	SoluMatrix diclofenac 35 mg Combined (n = 205)	SoluMatrix diclofenac 35 mg Combined (n = 500)	SoluMatrix diclofenac 35 mg Combined (N = 705)
Gastrointestinal Disorders			
Gastrointestinal ulcer	1 (0.5)	0	1 (0.1)
Perforation or Hemorrhage	0	1 (0.2)	1 (0.1)
Renal Disorders			
Serum creatinine elevation	6 (2.9)	5 (1.0)	11 (1.6)
Hypertension	9 (4.4)	12 (2.4)	21 (3.0)
Blood pressure increase	3 (1.5)	4 (0.8)	7 (1.0)
Renal failure	0	1 (0.2)	1 (0.1)
Hepatic Disorders			
Alanine aminotransferase elevation	4 (2.0)	21 (4.2)	25 (3.5)
Aspartate aminotransferase elevation	2 (1.0)	14 (2.8)	16 (2.3)
Abnormal liver function test	3 (1.5)	6 (1.2)	9 (1.3)
Hepatic enzyme increased	0	3 (0.6)	3 (0.4)
Transaminases increased	0	2 (0.4)	2 (0.3)
Hepatic enzyme abnormal	0	1 (0.2)	1 (0.1)
Cardiovascular Disorders			
Myocardial infarction	0	2 (0.4)	2 (0.3)
Stroke	0	0	0

Data presented as n (%).
AE = adverse event.
The denominator for the percentages is the number of patients in the safety population within each category. AEs were recorded from the time the patient signed the informed consent until the patient completed or withdrew from the clinical trial.

Conclusions: In pooled 12-week and 12-month phase 3 studies, a comparable proportion of SoluMatrix diclofenac-treated patients ≥65 years of age and <65 years of age experienced similar AEs. These data add to the growing SoluMatrix diclofenac safety experience.

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BMI, PAIN AND FUNCTION IN PATIENTS WITH KNEE OSTEOARTHRITIS

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Purpose: To evaluate the relationship between BMI and pain and function in patients with knee osteoarthritis (KOA) undergoing multiprofessional clinical treatment.

Methods: Thirty-eight patients (four men and 34 women) aged 47-83 years old (mean 63.2 years) in usual treatment for knee OA for more than three months, i.e. oral diacerhein and analgesics (according to pain), orthotics (when indicated) were selected for a two-days two months apart multiprofessional (medical, nutritional, psychological, physical and occupational therapy, physical educator and social workers) educational program on Ostearthritis. X-rays were performed to classify the OA degree (Kelgreen & Lawrence – K&L). All patients were evaluated at baseline (one month prior to first class) and at 6 months (3 months after the second class) with height, weight (BMI estimation), and asked to complete WOMAC, Lequesne, and visual analogue pain scale questionnaires.

Results: Eight patients had grade I (K&L), eleven, grade II, thirteen, grade III and six, grade IV. The results regarding change in VAS, WOMAC-pain, WOMAC and Lequesne did not correlate to the initial degree of osteoarthritis. There was no significant BMI variation in this study (average -0.2, SD= 0.22, range -4.9, 2.7). The higher the initial BMI, the lower the improvement in pain (Spearman test, $p = 0.03$). Pain did not improve significantly ($p = 0.2$). Function improved ($p < 0.001$) in inverse ratio to the initial BMI. However, the group that decreased BMI tended to improve pain and function and the group that increased BMI tended to improve pain and function (Kruskal-Wallis test, not significant).

Conclusions: BMI determines how patients will improve pain and function.

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GENDER DIFFERENCES IN THE RELATIONS BETWEEN CLINICAL QUESTIONNAIRES AND RADIOGRAPHIC GRADES IN KNEE OSTEOARTHRITIS. A CROSS-SECTIONAL EVALUATION OF 518 PATIENTS

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Purpose: To evaluate the correlations between common clinical OA diagnostic tools in order to determine the value of each. A secondary goal was to investigate the influence of gender differences on the findings.

Methods: Five hundred and eighteen patients with knee OA were evaluated using the Western Ontario and McMaster Osteoarthritis Index (WOMAC) questionnaire, short form 36 (SF-36) Health Survey and plain radiographs. Analysis of variance (ANOVA) was used to compare the different domains of the WOMAC and SF-36 questionnaires between genders and the radiographic scale.

Results: Higher knee OA x-ray grade were associated with worse clinical outcome: for women – higher scores for the WOMAC pain, function and final scores and lower scores in the SF-36 final score; in men: lower SF-36 overall and Physical domains scores. Gender differences were found in all clinical scores that were tested, with women having worse clinical scores for similar radiographic grading (p values< 0.001).

Conclusions: Knee radiographs for OA have an important role in the clinical evaluation of the patient. Patients with higher levels of knee OA in x-ray has a higher probability of having a worse clinical score in the WOMAC and SF-36 scores. The gender differences suggest that for similar knee OA x-ray grade women's clinical scores are lower.